K092794

510(k) Summary

Pursuant to 21 CFR 807.92c

SEP 13 2010

Submitted By: Andrew Rodenhouse
Transcorp, Inc.
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Date: September 10, 2010

Device Information:

Trade Name: Transcorp ACIF System
Common Name: Intervertebral Body Fusion Device
Classification: 21 CFR Section 888.3080, Product Code ODP, Class II

Predicate Devices:

K081730 Alphatec Novel Spinal Spacer System
P980048 BAK/C Vista Cervical Interbody Fusion Device

Device Description:

The Transcorp Anterior Cervical Intervertebral Fusion (ACIF) System includes various size implants manufactured from implant grade PEEK conforming to ASTM F2026-08. The implant is hollow to allow for autogenous bone graft material. The implant is provided non-sterile.

Intended Use:

The Transcorp ACIF System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as neck pain of discogenic origin with

the degeneration of the disc confirmed by history and radiographic studies. Transcorp ACIF implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autogenous bone graft. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The device must be used with supplemental fixation.

Performance Data:

Performance testing was performed on the Transcorp ACIF System. Static and dynamic axial compression, static and dynamic compression shear, static and dynamic torsion testing per ASTM F2077-03, and subsidence testing per ASTM F2267-04. A wear testing analysis was performed to determine particulate generation during dynamic axial compression and dynamic torsion testing. The wear debris was collected and analyzed per ASTM F1877-05. No clinical testing was performed.

Substantial Equivalence:

The Transcorp ACIF System is equivalent to the predicate devices in design, function, intended use, and indications for use. The results of non-clinical performance testing and analysis have demonstrated that the Transcorp ACIF System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Transcorp, Inc.
% Mr. Andrew Rodenhouse
1000 100th Street, SW – Suite F
Byron Center, Michigan 49315

SEP 13 2010

Re: K092794
Trade/Device Name: Transcorp ACIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: September 02, 2010
Received: September 02, 2010

Dear Mr. Rodenhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092794

Indications for Use Statement

510(k) Number: K092794

Device Name: Transcorp ACIF System

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Indications for Use:

The Transcorp ACIF System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. Transcorp ACIF implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autogenous bone graft. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The device must be used with supplemental fixation.

Prescription Use X or Over-the-counter use _____
(per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092794